

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON)
TALCUM POWDER PRODUCTS)
MARKETING, SALES PRACTICES AND) MDL Docket No. 2738
PRODUCTS LIABILITY LITIGATION)
)
)
)
This Document Relates To All Cases)
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DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON
CONSUMER INC.'S AMENDED GLOSSARY OF TECHNICAL TERMS
APPEARING IN DAUBERT BRIEFS

DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability
Partnership
600 Campus Drive
Florham Park, New Jersey 07932
(973) 549-7000

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
(202) 371-7000

Attorneys for Defendants Johnson &
Johnson and Johnson & Johnson
Consumer Inc.

AMENDED GLOSSARY¹

Actinolite: A mineral in the amphibole family.² Actinolite is the nonasbestiform version of the mineral. The asbestiform version is actinolite asbestos.

Agar: A gelatinous substance obtained from various kinds of red seaweed and used in biological culture media.³

AHERA: Asbestos Hazard Emergency Response Act

Allele frequencies: The relative frequency of an allele (variant of a gene) at a particular locus in a population, expressed as a fraction or percentage.⁴

Amphibole: A mineral group. Amphibole minerals are a family of double-chain hydrated silicate minerals. Along with serpentine, it is one of two families of minerals which, when the minerals are crystalized in a rare asbestiform habit, are regulated as asbestos.⁵

ANSI: American National Standards Institute

Anthophyllite: A mineral in the amphibole family.⁶ Anthophyllite is the nonasbestiform version of the mineral. The asbestiform version is anthophyllite asbestos.

Apoptosis: Programmed cell death.⁷

Asbestos: A collective term that describes a regulated group of six naturally occurring, highly fibrous silicate minerals that readily separate into thin, strong fibers that are flexible, heat resistant and chemically inert. The six minerals are

¹ The terms that did not appear in defendants' initial Glossary are noted in bold.

² (Wylie Rep. at 5.)

³ Oxford Concise Medical Dictionary (8th ed. 2010) (online version).

⁴ <https://www.nature.com/scitable/definition/allele-frequency-298>.

⁵ (See Wylie Rep. at 4-6.)

⁶ (*Id.* at 5.)

⁷ (Kurman Rep. at 17.)

regulated as asbestos when crystallized in a rare asbestiform habit. Asbestos falls into two families of minerals: serpentine and amphibole. Nonasbestiform serpentine and amphibole minerals are not regulated as asbestos.⁸

Asbestos-containing material: Environmental Protection Agency (EPA) term for any material that contains more than 1 percent asbestos by weight.⁹

Asbestiform: The habit of serpentine or amphibole minerals that have crystalized in a rare form with a specific type of mineral fibrosity in which the fibers possess high tensile strength and flexibility.¹⁰ Asbestiform minerals are regulated as asbestos. Nonasbestiform minerals are not “asbestos” or “asbestos minerals.”¹¹

Aspect Ratio: The ratio of a particle’s length to width. An object with a 3-to-1 (or “3:1”) aspect ratio has a length that is three times longer than its width.¹²

ASTM: American Society for Testing and Materials

Background levels of asbestos: The level of asbestos present in the air as a result of past mining of asbestos and the formerly common use of asbestos in buildings and products.¹³

Beneficiation: A process that improves the economic value of mined ore. In the case of talc, it may consist of “a variety of techniques that includes selective mining, hand sorting and milling by roller mills, hammer mills, ball mills, fluid energy mills and jet mills and are classified and separated from other minerals by

⁸ (See Wylie Rep. at 4-6.)

⁹ 15 U.S.C.A. § 2642(4).

¹⁰ (Dyar Rep. at 10, 11 (citing ISO 22262-1, -2, -3).)

¹¹ (Wylie Rep. at 6.)

¹² (Dyar Rep. at 3.)

¹³ Abelman et al., *Historical Ambient Airborne Asbestos Concentrations in the United States – An Analysis of Published and Unpublished Literature (1960s-2000s)*, 27(14) *Inhal. Toxicol.* 754 (2015) (attached as Ex. A1 to Tersigni Cert. (ECF No. 9723-2)).

froth flotation or magnetic separation.”¹⁴

Borderline ovarian tumors: Abnormal cells that form in the tissue covering the ovary. Borderline tumors are not cancer and are usually cured with surgery.¹⁵

BRCA 1/2: Tumor suppressing genes that normally act to restrain cell growth and protect DNA. When mutated, these genes increase a woman’s chances of breast and ovarian cancer.¹⁶

Bundles: A mineral morphology in which a particle occurs as separable groups of parallel fibers, often times with splayed ends and matted masses. At the end of a bundle, the fibers generally bend out like the straws at the end of a broom.¹⁷

CA-125: A protein that functions as an FDA-approved biomarker to monitor response to ovarian cancer treatment.¹⁸

Carcinomas: Tumors that originate in epithelial tissues.¹⁹

Catalase (“CAT”): A common anti-oxidant enzyme. A catalase-related single nucleotide polymorphism (“CAT SNP”) is a genetic variation in the DNA that code for the production of CAT proteins.²⁰

Cell proliferation: An increase in the size of a population of cells.²¹

¹⁴ Int’l Agency for Research on Cancer, World Health Org., 93 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc* 286 (2010) (“IARC 2010 Monograph”). (See Poulton Rep. at 5.)

¹⁵ [Cancer Research UK, *Borderline Ovarian Tumours*](https://www.cancerresearchuk.org/about-cancer/ovarian-cancer/types/borderline),
<https://www.cancerresearchuk.org/about-cancer/ovarian-cancer/types/borderline>
(last reviewed Jan. 17, 2019).

¹⁶ (Birrer Rep. at 3; Shih Rep. at 3.)

¹⁷ (Dyar Rep. at 53, 54.)

¹⁸ (See Shih Rep. at 5; Boyd Rep. at 9.)

¹⁹ (Neel Rep. at 9.)

²⁰ (See Boyd Rep. at 11, 13, 16.)

²¹ Oxford Concise Medical Dictionary (8th ed. 2010) (online version).

Clear cell carcinoma: Cancer characterized by inactivating mutations in the tumor suppressor gene ARID1A;²² tumors are related to endometrioid carcinoma, but the cells contain clear cytoplasm and also arise from endometriosis.²³

Cleavage Fragments: Microscopic fragments of nonasbestiform amphibole minerals that form when amphibole minerals are crushed, as, for example, in the mining and milling of ores. These particles break along cleavage planes and often appear as elongated particles. Cleavage fragments are not asbestos.²⁴

Colorimetric assay: A technique used to determine the concentration of a substance by measuring the amount of light absorbed by the substance or by a product of the enzymatic reaction promoted by the substance.

Confidence interval (“95% CI”): A range of values within which the results would be expected to fall 95% of the time if a study were repeated. When this range includes 1.0, the implication is that the possibility of no association cannot be ruled out, and the result is not considered statistically significant.²⁵

Crocidolite: A mineral in the amphibole family. Crocidolite is the asbestiform version of the mineral. The nonasbestiform version is riebeckite.²⁶

Cummingtonite: A mineral in the amphibole family.²⁷ Cummingtonite is the nonasbestiform version of the mineral. The asbestiform version is amosite.²⁸

Cytokines: Substances secreted by cells that send messages to other cells of the immune system and can cause these and other cell types in the area to proliferate or

²² (Birrer Rep. at 4.)

²³ (Kurman Rep. at 28.)

²⁴ (Wylie Rep. at 9-10.)

²⁵ (Diette Rep. at 7; Holcomb Rep. at 19.)

²⁶ (*Id.* at 5, 6.)

²⁷ (Dyar Rep. at 9.)

²⁸ (Wiley Rep. at 23.)

divide as a natural defense mechanism.²⁹

D-Spacing: The spacing between the pattern of dots created by SAED. When properly analyzed, *d*-spacing values can identify the crystal structure of a specimen.³⁰

Diffraction Pattern: A pattern of dots created by SAED, corresponding to spacing between the atoms of a specimen, which can be used to identify a specimen's crystal structure. This analysis is done using the "*d*-spacing" and angles between the dots.³¹

DMSO (dimethyl sulfoxide): A solvent used in some laboratory experiments, usually to dissolve organic material.³²

EDXA/EDS: Energy Dispersive X-ray Analysis/Energy Dispersive Spectroscopy

Endometriosis: A condition involving abnormal growth of endometrial tissue and a risk factor for clear cell and endometrioid ovarian cancer, but not other ovarian cancer subtypes.³³

Energy Dispersive X-Ray Analysis ("EDXA"): An analytical technique that can be performed with a transmission electron microscope to provide information about the chemical composition of a specimen.³⁴ Energy Dispersive X-Ray Analysis ("EDXA") is synonymous with Energy Dispersive Spectroscopy ("EDS").

Epithelial tissues: Tissues originating in the ectoderm that are typically found on the outer layer of an organ.³⁵

²⁹ (Mossman Rep. at 8.)

³⁰ (Dyar Rep. at 28.)

³¹ (*Id.*)

³² (Boyd Rep. at 4.)

³³ (Neel Rep. at 13; *see also* Kurman Rep. at 9-10.)

³⁴ (Dyar Rep. at 14, 28.)

³⁵ (*See generally* Neel Rep. at 9.)

Elongated talc particles: Fibrous talcs that do not contain asbestos fibers. These particles have not been classified as human carcinogens³⁶ and are “structurally and chemically different from asbestos or asbestiform fibers.”³⁷

Endometrioid carcinoma: Cancer characterized by mutations with the PI3 kinase pathway and CTNNB1;³⁸ tumors bear a resemblance to the endometrium (lining of the uterine cavity) and arise from endometriosis or an endometriotic cyst.³⁹

Epithelial ovarian cancers: The most common ovarian malignancies, which include several different histologic types, including high grade serous ovarian cancer, low grade serous ovarian cancer, mucinous carcinoma, endometrioid carcinoma and clear cell carcinoma.⁴⁰

Fibrous talc: Talc intergrown with or contaminated by true asbestos, or, at the very least, talc that grows in an asbestiform habit. “Fibrous talcs not containing asbestos fibers have not been classified as human carcinogens⁴¹ and are structurally and chemically different from asbestos or asbestiform fibers.”⁴²

Gene expression: The process by which genetic code, known as genes, creates different types and quantities of messenger RNA (often abbreviated in scientific writing as “mRNA”), and, as a result, different types and quantities of proteins.⁴³

Genitourinary tract: The area of the body encompassing the reproductive organs.⁴⁴

Genome-wide association study (“GWAS”): Study that tests common genetic variants for associations with a trait, including disease risk.⁴⁵

³⁶ (IARC 2010 Monograph at 412.)

³⁷ (Mossman Rep. at 23.)

³⁸ (Birrer Rep. at 3-4; *see also* Kurman Rep. at 7.)

³⁹ (Kurman Rep. at 28.)

⁴⁰ (*Id.* at 2.)

⁴¹ (IARC 2010 Monograph at 412.)

⁴² (Mossman Rep. at 23.)

⁴³ (*See* Neel Rep. at 4; *see also* Boyd Rep. at 11.)

⁴⁴ (Neel Rep. at 16.)

Genome-wide significance: An association between a genetic variant and a disease that is revealed through research to be sufficiently strongly related to cancer risk as to reflect an established association.⁴⁶

Genotoxicity: A genetic term that refers to a destructive effect on a cell's DNA or RNA. Genotoxic agents generally fall into three categories: 1) carcinogens, or cancer-causing; 2) mutagens, or mutation causing; and 3) teratogens, or causing birth defects. Genotoxins can affect either germ cells (i.e., sperm or egg cells) or somatic cells (adult cells).⁴⁷

Granulomas: A nodular aggregation of mononuclear inflammatory cells, generally macrophages reassembling epithelial cells (epithelioid cells), usually surrounded by a rim of lymphocytes, often with multinucleated giant cells.⁴⁸

Group 1 carcinogen: A designation by the International Agency for Research on Cancer (IARC) given to agents IARC has deemed "carcinogenic to humans."⁴⁹

Habit: Mineralogical term specifying the physical form a mineral takes when it forms (grows) in nature, e.g., globular, granular, prismatic, fibrous. The habit of growth of asbestos is referred to as asbestiform.⁵⁰

High grade serous ovarian cancer ("HGSOC"): Also known as high-grade serous carcinoma. The most common and lethal type of ovarian cancer; arises primarily

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⁴⁵ European Bioinformatics Institute, *What are genome wide association studies (GWAS)?*, <https://www.ebi.ac.uk/training/online/course/gwas-catalog-exploring-snp-trait-associations/why-do-we-need-gwas-catalog/what-are-genome>. (See also Neel Rep. at 7, 23.)

⁴⁶ (Neel Rep. at 7.)

⁴⁷ (Tuttle Rep. at 12 (citation omitted).)

⁴⁸ (Kurman Rep. at 28.)

⁴⁹ World Health Org., Int'l Agency for Research on Cancer, Agents Classified by the IARC Monographs, Volumes 1–124, <https://monographs.iarc.fr/agents-classified-by-the-iarc/> (last updated Sept. 23, 2019).

⁵⁰ (Wylie Rep. at 6.)

from the fallopian tube; and occurs when the DNA repair process is compromised by inactivating mutations in p53 and BRCA1/2 genes.⁵¹

IARC: World Health Organization's International Agency for Research on Cancer

IRRSST: Robert-Sauve Research Institute in Occupational Health and Safety

ISO: International Organization for Standardization

Low grade serous ovarian cancer ("LGSOC"): Also known as low grade serous carcinoma. Refers to noninvasive (niLGSC) or invasive (LGSC) tumors that develop in a stepwise fashion, beginning with a benign proliferative tumor that displays a minimal degree of cytologic atypia to a noninvasive low-grade serous carcinoma (niLGSC) and then to an invasive low-grade serous carcinoma.⁵²

Macrophage: A type of cell present in connective tissue that can multiply or change in function at sites of deposition of particles or microorganisms, the normal function of which is to clear particles, a process known as "phagocytosis."⁵³

MAS: Materials Analytical Services, LLC (Dr. Longo & Dr. Rigler's laboratory)

Morphology: The form or shape of a crystal or mineral aggregate.⁵⁴

MSHA: U.S. Mine Safety and Health Administration

MTT cell proliferation assay: A colorimetric assay that measures metabolic activity, as an indirect measure of cell count.⁵⁵

Mucin 1 ("MUC1"): A membrane-bound glycoprotein present on most epithelial cells.⁵⁶

⁵¹ (Birrer Rep. at 3, 4; *see also* Kurman Rep. at 5.)

⁵² (Kurman Rep. at 3-4; Birrer Rep. at 3.)

⁵³ (Mossman Rep. at 8.)

⁵⁴ (*See* Dyar Rep. at 28.)

⁵⁵ (Birrer Rep. at 25.)

⁵⁶ (Moore Rep. at 37.)

Mucinous carcinoma: Tumors characterized by *ras* mutations,⁵⁷ abundant mucin in cells and a superficial resemblance to gastrointestinal tumors.⁵⁸

Neoplastic changes: The transformation of a normal cell into a cancer cell.

Neoplastic transformation assay: Any one of a series of well-established tests for neoplastic transformation. These tests include a test for loss of contact-inhibition in a petri dish and a test for anchorage-independent growth potential in a soft agar suspension, but the best and most accepted is a test for tumor-formation potential after injection in immunocompromised mice.⁵⁹

NIOSH: National Institute for Occupational Safety and Health (OSHA's scientific and research arm)

Nonasbestiform: A crystal habit that is not asbestiform. Serpentine and amphibole minerals that are nonasbestiform are not regulated as asbestos.

Oxidative stress: A situation in which greater amounts of free radicals and reactive forms of oxygen are present than can be utilized or neutralized by an organism, potentially resulting in damage to proteins, lipids, DNA, etc.⁶⁰

p53 (or TP53): A tumor suppressor gene and the protein for which it encodes. Known, because of its critical importance, as the "guardian of the genome."⁶¹ P53 gene mutations are present in virtually all Type II ovarian cancers, including high-grade serous, and are generally the first such mutations to be present.⁶²

⁵⁷ *Ras* mutations are mutations in genes that are part of a family of genes referred to as the RAS family; mutations in these genes are responsible for a large number of tumors. See National Cancer Institute, *About the RAS Initiative*, <https://www.cancer.gov/research/key-initiatives/ras/about>. Mucins are proteins that make up mucus.

⁵⁸ (Birrer Rep. at 4; Kurman Rep. at 28.)

⁵⁹ (See Boyd Rep. at 19; Birrer Rep. at 15.)

⁶⁰ Oxford Concise Medical Dictionary (8th ed. 2010) (online version).

⁶¹ (See Neel Rep. at 6.)

⁶² (See *id.* at 12; Shih Rep. at 13.)

P-value: A measure of the likelihood that results occurred due to chance.⁶³

Permissible exposure limit (PEL): The level of exposure to an agent that the Occupational Safety and Health Administration (OSHA) deems protective of worker safety and health over a working lifetime. OSHA’s PEL for asbestos exposure is 0.1 asbestos fibers per cubic centimeter of air as an eight-hour time weighted average (TWA).⁶⁴

Pleurodesis: A procedure that involves the direct injection of .5 to 10 grams of an agent such as talc directly into the cavity surrounding the lungs (pleural cavity) to stimulate scarring and thereby prevent the future build-up of air or fluid in this space. These conditions, called pneumothorax or pleural effusion, respectively, sometimes occur as a result of lung cancer and other conditions.⁶⁵

PLM: Polarized Light Microscope

Point mutations: Mutations that affect single DNA residues, and depending upon their precise location, may have distinct effects. If they affect coding regions of genes, point mutations can increase (“gain-of-function”) or decrease (“loss-of-function”) a protein’s normal activity. Alternatively, point mutations can affect key regulatory regions.⁶⁶

Polarized Light Microscopy (“PLM”): A technique that uses a specially-equipped microscope to pass polarized beams of light through a mineral sample.⁶⁷ PLM is used to detect and identify the optical properties of asbestos in bulk samples.⁶⁸

Proliferation assay: One of several well-established methods for determining cellular proliferation – i.e., cell growth and division.⁶⁹

⁶³ (Ballman Rep. at 17.)

⁶⁴ (Moore Rep. at 47.) *See also* U.S. Dep’t of Labor, Occupational Safety & Health Admin., *OSHA Fact Sheet* (2014), <https://www.osha.gov/Publications/OSHA3507.pdf>.

⁶⁵ (Holcomb Rep. at 18.)

⁶⁶ (Neel Rep. at 5.)

⁶⁷ (Dyar Rep. at 43-44.)

⁶⁸ (Wylie Rep. at 1, 2.)

Raman spectroscopy: Spectroscopy in which Raman particle scattering is used to investigate molecular energy levels.⁷⁰

Reactive oxygen species (i.e., the “redox balance”): Agents or conditions that can result in the production of “reactive oxygen species” (“ROS”), which can damage DNA and lead to mutations under certain conditions.⁷¹

Riebeckite: A mineral in the amphibole family.⁷² Riebeckite is the nonasbestiform version of the mineral. The asbestiform version is crocidolite.⁷³

Seeded: Placed in petri dishes for culturing.

Selected Area Electron Diffraction (“SAED”): A technique that can be performed with a transmission electron microscope to produce a diffraction pattern that can be analyzed to identify a specimen’s crystal structure.⁷⁴

SEM: Scanning Electron Microscope

Serous tubal intraepithelial carcinoma (STIC) lesion: A precursor lesion to high grade serous ovarian cancer.⁷⁵

Serpentine: A mineral group that, like amphibole, contains common rock-forming minerals and occurs rarely as asbestos.⁷⁶ Along with amphibole, it is one of two

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⁶⁹ See generally Hillegass et al., *Assessing Nanotoxicity in Cells In Vitro*, *WIREs Nanomedicine and Nanobiotechnology*, 2(3) Wiley Interdiscip Rev Nanomed Nanobiotechnol. 219 (2009).

⁷⁰ Oxford Concise Medical Dictionary (8th ed. 2010) (online version).

⁷¹ (Neel Rep. at 8.)

⁷² (Dyar Rep. at 9.)

⁷³ (Wiley Rep. at 6.)

⁷⁴ (Dyar Rep. at 28.)

⁷⁵ (Neel Rep. at 11, 21.)

⁷⁶ (Wylie Rep. at 4.)

families of minerals which, when the minerals are crystalized into a rare asbestiform habit, are regulated as asbestos.⁷⁷

Sex cord-stromal tumors: Tumors that arise from the tissues that surround and support the germ cells. These tissues include granulosa cells and theca cells (which support developing follicles) and fibrocytes (which are precursors to connective tissue cells).⁷⁸

Single nucleotide polymorphisms (“SNPs”): Genetic variations that occur throughout a person’s DNA.⁷⁹

Staging: A system used by pathologists to reflect a tumor’s size and the extent to which it has spread beyond its initial tissue boundary; each tumor type has its own staging system, which usually goes from Stage I to IV.⁸⁰

Statistical Power: The likelihood of a study detecting an association when there is an association to be detected.⁸¹

Transmission Electron Microscope (“TEM”): A type of electron microscope capable of producing information by passing electrons through a specimen, including a two-dimensional image of a specimen (visual TEM), information relating to a specimen’s chemical composition (EDXA), and information relating to a specimen’s arrangement of atoms (SAED).⁸²

Tremolite: A mineral in the amphibole family. Tremolite is the nonasbestiform version of the mineral. The asbestiform version is tremolite asbestos.⁸³

TSCA: Toxic Substances Control Act

⁷⁷ (See Dyar Rep. at 8 & Tbl. 1.)

⁷⁸ (Neel Rep. at 10.)

⁷⁹ (*Id.* at 7.)

⁸⁰ (*Id.* at 9.)

⁸¹ (Ballman Rep. at 6.)

⁸² (See Dyar Rep. at 1-3, 28.)

⁸³ (Wylie Rep. at 5, 7.)

Tumor grade: A system used by pathologists to reflect the extent to which a tumor cell has lost the differentiated features of the cell of origin.⁸⁴

Tumorigenic cells: Cells that are capable of forming or tending to form tumors.⁸⁵

USGS: United States Geological Survey

Well plate: A plate or block containing multiple small wells or cavities used for analysis.

Zone-Axis: An area where two crystal faces intersect.⁸⁶

Zone-Axis Orientation: The direct crystal axis that is parallel to the electron beam at the orientation when the SAED pattern is recorded.⁸⁷

⁸⁴ (Neel Rep. at 9.)

⁸⁵ Oxford Concise Medical Dictionary (8th ed. 2010) (online version).

⁸⁶ (See Dyar Rep. at 2.)

⁸⁷ (*Id.* at 2, n.2.)